Ortho-Clinical Diagnostics
a Johnson-Johnson company
100 Indigo Creek Drive
Rochester, New York 14626-5101

NOV 16 2006

5.0 510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K062123

1. **Submitter name, address, contact**

Ortho-Clinical Diagnostics, Inc.
100 Indigo Creek Drive
Rochester, New York 14626-5101
(585) 453-3143
Contact Person: Michael Byrne

2. **Preparation Date**

July 24, 2006

3. **Device name**

Trade or Proprietary Names:
VITROS Chemistry Products COCM Reagent
VITROS Chemistry Products Calibrator Kit 26
VITROS Chemistry Products FS Calibrator 1
VITROS Chemistry Products DAT Performance Verifiers I, II, III, IV, and V

Common Names:
COCM assay and controls

Classification Names:
Cocaine and cocaine metabolite test system (862.3250) Class II;
Clinical toxicology calibrators (862.3200) Class II;
Clinical toxicology control material (862.3280) Class I (general controls). Since these devices (VITROS DAT Performance Verifiers I, II, III, IV, & V) are assayed controls, they meet the reserved criteria under Section 510(l) of the Food, Drug, and Cosmetic Act.

Continued on next page

4. Predicate Devices

The VITROS Chemistry Products COCM assay is substantially equivalent to the previously cleared Syva® Emit® II Plus Cocaine Metabolite assay (K031512).

The VITROS Chemistry Products DAT Performance Verifiers are substantially equivalent to the previously cleared Liquichek™ Urine Toxicology Control Levels S1E and S2E (K022707).

5. Device description

The VITROS COCM assay is a homogeneous enzyme immunoassay that is performed using the VITROS Chemistry Products COCM Reagent with the VITROS Chemistry Products Calibrator Kit 26, VITROS Chemistry Products FS Calibrator 1, and VITROS Chemistry Products FS Diluent Pack 4 (DAT Diluent / DAT Diluent 2) on VITROS 5,1 FS Chemistry Systems.

The VITROS COCM Reagent is a dual chambered package containing ready-to-use liquid reagents that are used to detect benzoylecgonine (cocaine metabolite) in urine. Sample, calibrators, and controls are automatically treated with surfactant (DAT Diluent 2) prior to addition of reagents. Treated sample is added to Reagent 1 containing antibody reactive to benzoylecgonine, glucose-6-phosphate and nicotinamide adenine dinucleotide (NAD+), followed by Reagent 2 containing benzoylecgonine labeled with the enzyme glucose-6-phosphate dehydrogenase (G6P-DH). The assay is based on competition between benzoylecgonine in the treated urine sample and benzoylecgonine labeled with the enzyme glucose-6-phosphate dehydrogenase (G6P-DH) for antibody binding sites. Enzyme activity decreases upon binding to the antibody, therefore the concentration of benzoylecgonine in the urine sample is directly proportional to measured enzyme activity. Active enzyme converts oxidized nicotinamide adenine dinucleotide (NAD+) to NADH, resulting in an absorbance change that is measured spectrophotometrically at 340 nm.

The VITROS Chemistry Products Calibrator Kit 26 is prepared from human urine to which drugs of abuse, metabolites of drugs of abuse, organic salt, surfactants, and preservative have been added. The VITROS Chemistry Products FS Calibrator 1 is composed of processed water and 0.9% w/v sodium chloride (Saline). These calibrators are used in combination to calibrate VITROS 5,1 FS Chemistry Systems for the qualitative or semi-quantitative measurement of benzoylecgonine (cocaine metabolites) in urine.

The VITROS Chemistry Products DAT Performance Verifiers I, II, III, IV, and V are prepared from a human urine pool to which analytes, surfactant, and preservative have been added. These are assayed controls used to monitor performance of the VITROS COCM assay on VITROS 5,1 FS Chemistry Systems.

Continued on next page

The VITROS Chemistry Products FS Diluent Pack 4 (DAT Diluent / DAT Diluent 2) is a common reagent that is used by multiple assays on the VITROS 5,1 FS Chemistry System. This is a dual chambered package containing two ready-to-use liquid diluents. Diluent 1 is prepared from processed water to which inorganic salt has been added. DAT Diluent 2 is prepared from processed water to which surfactant and preservative have been added.

The VITROS 5,1 FS Chemistry System is a clinical chemistry instrument that provides automated use of the VITROS Chemistry Products MicroTip® and MicroSlides® range of products. The VITROS 5,1 FS System was cleared for market by 510(k) premarket notification (K031924).

6. Device intended uses

VITROS Chemistry Products COCM Reagent: For *in vitro* diagnostic use only. VITROS Chemistry Products COCM Reagent is used on VITROS 5,1 FS Chemistry Systems for the semi-quantitative or qualitative determination of benzoylecgonine (cocaine metabolites) in human urine using a cutoff of either a 150 ng/mL or a 300 ng/mL. Measurements obtained with the VITROS COCM method are used in the diagnosis and treatment of cocaine use or overdose.

The VITROS Chemistry Products COCM assay is intended for use by professional laboratory personnel. It provides only a preliminary test result. A more specific alternative chemical method must be used to confirm a result obtained with this assay. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug-of-abuse test result, particularly when evaluating a preliminary positive result.

VITROS Chemistry Products Calibrator Kit 26: For *in vitro* diagnostic use only. VITROS Chemistry Products Calibrator Kit 26 is used to calibrate VITROS 5,1 FS Chemistry Systems for the qualitative or semi-quantitative measurement of drugs of abuse.

VITROS Chemistry Products FS Calibrator 1: For *in vitro* diagnostic use only. VITROS Chemistry Products FS Calibrator 1 is used in conjunction with VITROS Chemistry Products Calibrator Kits to calibrate VITROS 5,1 FS Chemistry Systems.

VITROS Chemistry Products DAT Performance Verifiers I, II, III, IV & V: For *in vitro* diagnostic use only. VITROS Chemistry Products DAT Performance Verifiers are assayed controls used to monitor performance of urine drugs of abuse screening assays on VITROS 5,1 FS Chemistry Systems.

7. Comparison to predicate devices: The VITROS Chemistry Products COCM Reagent and the VITROS Chemistry Products Calibrator Kit 26 used in conjunction with VITROS FS Calibrator 1 (VITROS Chemistry Products COCM Assay) are substantially equivalent to the Syva® Emit® II Plus Cocaine Metabolite assay (predicate device) which was cleared by the FDA for IVD use (K031512).

The performance of the VITROS COCM assay on the VITROS 5,1 FS Chemistry System was compared to the Syva® Emit® II Plus Cocaine Metabolite assay. The results demonstrated good agreement between the two immunoassay methods.

The VITROS Chemistry Products DAT Performance Verifiers I, II, III, IV, & V are substantially equivalent to the Liquichek™ Urine Toxicology Control Levels S1E and S2E (predicate device) which were cleared by the FDA for IVD use (K022707).

In addition to correlation studies, bench testing was performed to determine assay precision, linearity, specificity, expected values, limit of detection, dilution, stability, and specimen matrix of the VITROS COCM assay.

Table 1 Similarities and differences of the assays performed using the VITROS COCM assay and the Syva® Emit® II Plus Cocaine Metabolite assay.

Device Similarities	
Device Characteristic	**Description**
Indications for Use	For *in vitro* diagnostic use only. The assays are intended for use in the semi-quantitative or qualitative determination of benzoylecgonine (cocaine metabolites) in human urine.
Test Principle	Homogeneous enzyme immunoassay
Cut-Off values	150 and 300 ng/mL
Specimen Type	Human Urine
Reagent Format	Liquid ready to use
Antibody source	Sheep polyclonal antibodies reactive to benzoylecgonine
Calibration traceability	Benzoylecgonine, nominal values confirmed by GC/MS
Calibrator matrix	Human urine

Device Differences		
Device Characteristic	**Description**	
	VITROS COCM assay (New device)	**Syva® Emit® II Plus Cocaine Metabolite assay (Predicate device)**
Reportable Range	50 – 1000 ng/ml	45 – 900 ng/mL
Calibrator levels	Six levels	Qualitative: Three levels Semi-quantitative: Five levels
Calibrator format	Frozen: liquid ready to use	Refrigerated: liquid ready to use
Instrumentation	VITROS 5,1 FS Chemistry System	Multiple automated clinical chemistry systems

Table 2 Similarities and differences of the device characteristics between the VITROS DAT Performance Verifiers I, II, III, IV, and V with the predicate device Liquichek™ Urine Toxicology Control Levels S1E and S2E.

Device Similarities		
Device Characteristic	**Description**	
Matrix	Human Urine	
Format	Liquid, ready to use	
Device Differences		
Device Characteristic	**Description**	
	VITROS DAT Performance Verifiers (New Device)	**Bio-Rad Liquichek Urine Toxicology Control**
Analytes Reported	Amphetamines (d-Methamphetamine), Barbiturates (Secobarbitol), Benzodiazepines (Lormetazepam), Cannabinoids (THC), Cocaine (Benzoylecgonine), Methadone, Opiates (Morphine), Phencyclidine, Propoxyphene.	Amphetamines (d-Methamphetamine), Barbiturates (Secobarbitol), Benzodiazepines (Lormetazepam), Cannabinoids (THC), Cocaine (Benzoylecgonine), Ethanol, Lysergic Acid Diethylamide (LSD), Methadone, Methaqualone, Opiates (Morphine), Phencyclidine, Propoxyphene, Tricyclic Antidepressants (Nortriptyline) and addition of creatinine, and adjustment of pH, and specific gravity
Levels	Five	Two

8. Conclusions The data presented in the premarket notification provide a reasonable assurance that the VITROS Chemistry Products COCM Reagent, VITROS Chemistry Products Calibrator Kit 26 used in conjunction with VITROS Chemistry Products FS Calibrator 1, and the VITROS Chemistry Products DAT Performance Verifiers are safe and effective for the stated intended uses and are substantially equivalent to the cleared predicate devices. Equivalence to the predicates was demonstrated using a commercially available assay along with patient samples.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. Michael M. Byrne
Regulatory Affairs Associate
Ortho-Clinical Diagnostics
100 Indigo Creek
Rochester, NY 14626

NOV 16 2006

Re: k062123
Trade/Device Name: VITROS Chemistry Products COCM Reagent
Regulation Number: 21 CFR 862.3650
Regulation Name: Opiate test system
Regulatory Class: Class II
Product Code: DIO, DKB, DIF
Dated: September 26, 2006
Received: September 28, 2006

Dear Mr. Byrne:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Alberto Gutierrez, Ph.D.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K062123

Device Name: VITROS Chemistry Products COCM Reagent

Indications for Use: For *in vitro* diagnostic use only. VITROS Chemistry Products COCM Reagent is used on VITROS 5,1 FS Chemistry Systems for the semi-quantitative or qualitative determination of benzoylecgonine (cocaine metabolite) in human urine using a cutoff of either a 150 ng/mL or a 300 ng/mL. Measurements obtained with the VITROS COCM method are used in the diagnosis and treatment of cocaine use or overdose.

The VITROS Chemistry Products COCM assay is intended for use by professional laboratory personnel. It provides only a preliminary test result. A more specific alternative chemical method must be used to confirm a result obtained with this assay. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug-of-abuse test result, particularly when evaluating a preliminary positive result.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol C Benson

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

K062123

Indications for Use

510(k) Number (if known): K062123

Device Name: VITROS Chemistry Products Calibrator Kit 26
VITROS Chemistry Products FS Calibrator 1
VITROS Chemistry Products DAT Performance Verifiers I, II, III, IV, and V

Indications for Use:

For *in vitro* diagnostic use only. VITROS Chemistry Products Calibrator Kit 26 is used to calibrate VITROS 5,1 FS Chemistry Systems for the qualitative or semi-quantitative measurement of drugs of abuse.

For *in vitro* diagnostic use only. VITROS Chemistry Products FS Calibrator 1 is used in conjunction with VITROS Chemistry Products Calibrator Kits to calibrate VITROS 5,1 FS Chemistry Systems.

For *in vitro* diagnostic use only. VITROS Chemistry Products DAT Performance Verifiers are assayed controls used to monitor performance of urine drugs of abuse screening assays on VITROS 5,1 FS Chemistry Systems.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol Benson
Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K062123